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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,970	03/28/2002	Alexander Fred Markham	9052-87	8326
20792	7590	08/18/2005	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC			SULLIVAN, DANIEL M	
PO BOX 37428			ART UNIT	
RALEIGH, NC 27627			PAPER NUMBER	

1636

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,970

Applicant(s)

MARKHAM ET AL.

Examiner

Daniel M. Sullivan

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7,9,11,12,14,25-27,29 and 31-46 is/are pending in the application.
- 4a) Of the above claim(s) 9,11,12,14,25-27 and 31-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 July 2005 has been entered.

Claims 9, 11, 12, 14, 25-27 and 31-46 had been withdrawn from consideration and claims 1-4, 7 and 28-30 were considered in the Final Office Action mailed 24 January 2005. Claims 2, 3, 28 and 30 were canceled and claims 1, 4, 7 and 29 were amended in the 22 July Paper. Claims 1, 4, 7, 9, 11, 12, 14, 25-27, 29 and 31-46 are pending and claims 1, 4, 7 and 29 are under consideration.

Response to Amendment and Arguments**Claim Rejections - 35 USC § 112**

Claims 1, 4, 7 and 29 **stand rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record.

The previous Office Actions assert that the skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of any nucleic acid nucleic acid having at least 95% homology to SEQ ID NO: 1 and “essentially the same biological properties as the disclosed latency

Art Unit: 1636

promoter". The Office contends that only the described nucleic acid comprising at least 630 base pairs of sequence immediately upstream of the initiation codon of ORF73 as set forth in SEQ ID NO: 1 meet the written description provision of 35 U.S.C. §112, first paragraph.

In response to the *prima facie* case and arguments of record, Applicant has amended claim 1 and claim 7 such that "the latency promoter is encoded by at least 329 bp and up to 2,000 bp of a nucleic acid sequence immediately upstream of an initiation codon of open reading frame (ORF) 73 of SEQ ID NO: 1." Applicant submits that the skilled artisan would be able to readily envision a genus of nucleotide sequences having characteristics recited in the claims based on the disclosure.

These arguments have been fully considered but are not deemed persuasive. As amended, the claim does not require that the claimed nucleic acid comprise any of the sequence set forth as SEQ ID NO: 1. Instead, the claims can be broadly construed as limited to a nucleic acid comprising a latency promoter encoded by 329 bp and up to 2,000 bp of a (any) nucleic acid sequence immediately upstream of an (any) initiation codon of ORF73, wherein the initiation codon is set forth in SEQ ID NO: 1. The application clearly does not describe a latency promoter commensurate with the scope of what is now claimed. For reasons of record, only the described nucleic acid comprising at least 630 base pairs of sequence immediately upstream of the initiation codon of ORF73 as set forth in SEQ ID NO: 1 meet the written description provision of 35 U.S.C. §112, first paragraph. In the interest of clarity, Applicant is urged to recite specifically which portion of SEQ ID NO: 1 is comprised by the claimed nucleic acid (*e.g.*, the nucleotide sequence set forth as nucleotides 1,370-2,000 of SEQ ID NO: 1).

Claim Rejections - 35 USC § 102

Claims 1-3, 4, 7 and 28-30 **stand rejected** under 35 U.S.C. 102(b) as being anticipated by Nicholas *et al.* (1992) *Virol.* 188:296-310 as evidenced by Entrez Nucleotide Database Accession No. M86409 for reasons of record.

In response to the *prima facie* case and arguments of record, Applicant has amended claims 1 and 7 to recite that “the latency promoter is encoded by at least 329 bp and up to 2,000 bp of a nucleic acid sequence immediately upstream of an initiation codon of open reading frame (ORF) 73 of SEQ ID NO: 1.” Applicant contends that the disclosure of Nicholas *et al.* is not enabling for what is presently claimed. These arguments were addressed in the paragraph bridging pages 5-6 of the previous Office Action.

Applicant further argues that Nicholas *et al.* does not teach each and every recitation of the claims as amended. This argument has been fully considered but is not deemed persuasive. As stated in the Office Action mailed 27 May 2004, claims that further limit the latency promoter coding portion of the claimed nucleic acid, as opposed to the claimed nucleic acid itself, to a certain specified length does not distinguish the claimed nucleic acid from the nucleic acid comprised in the composition of Nicholas *et al.* The size limitation is inherent to the promoter comprised by the nucleic acid of Nicholas *et al.* because the promoter sequence disclosed thereby is the same as the promoter sequence disclosed in the instant application. Although the nucleic acid in which the promoter sequence is comprised is longer than 2,000 base pairs, the portion of that DNA encoding the promoter itself would be constant unless one were to

Art Unit: 1636

insert sequence into or delete sequence from the portion of the molecule that actually encodes the promoter.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 USC §102.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.
Examiner
Art Unit 1636


DANIEL M. SULLIVAN
PATENT EXAMINER